

REMARKS

A. Preliminary Statement/Examiner Interview/Status of Claims

Applicants note that in the subject Action, claim 121 was rejected only on the basis of obviousness-type double patenting over copending application 10/439,252. Accordingly, it is Applicants intention to proceed with amendments herein, based on claim 121, to place the present case in condition for allowance.

On May 25, 2006, the Examiner and Applicant's representative conducted a telephonic interview in order to discuss the remaining issues. During that interview, Applicant's representative advised the Examiner of Applicant's desire to proceed with the subject matter of claim 121. The Examiner agreed that claim 121, as presented generally in the un-entered amendment of October 24, 2005, would be allowable. However, the Examiner noted many instances where the claims were said to be confusing and lacking of clarity, and that these issues needed to be addressed in order to proceed to allowance. The present amendment is thus made to address the issues of clarity discussed with the Examiner.

Accordingly, claim 121 has been placed into independent form by introducing the subject matter of previous main claim 97. It will be noted that the claim is slightly modified from the language of previous claim 97 simply to make it more readable. However, amended claim 121 does now refer to the inclusion of "a pharmacologically active agent," support for which can be found in the specification beginning at page 19, line 28 ("a pharmacologically active agent"), and extending through page 20.

Claim 94 is canceled as duplicative of claim 150.

Claim 95 is canceled as potentially confusing in its use of "virtually."

Claims 111 and 113-117 were canceled as confusing in that they suggested that the various substances referred to in those claims were dipolar aprotic solvents. The claims were intended to simply include the listed elements as being in addition to the dipolar aprotic solvent. Nevertheless, it was believed that the claims were nevertheless confusing and have thusly been canceled.

Claims 123-130 were canceled for essentially the same reason, i.e., that they were confusing in their scope and interpretation, and as being potentially redundant of the subject matter of other claims, such as claims 144-148.

Claims 133, 136 and 137 were canceled as duplicative of other claims.

It will be noted that the term “aqueous secondary solvent” has generally been removed as confusing with respect to the “aqueous solvent” that is used to reconstitute the vehicle. Thus, the first step of the principal claim now simply refers to the preparation of a “solvent mixture” comprising various elements, including elements that are referred in the specification as aqueous secondary solvent compositions. It is believed that this amendment to claim 121 and others will make the claims more readable and comprehensible.

New claim 152 is added to specify “pimaricin” as the pharmacologically active agent. The addition of claim 152 now requires the reintroduction of Elias J. Anaissie as an inventor, as discussed below.

New claims 153 and 154 specify isosmotic and hypertonic vehicles, support for which can again be found beginning at page 19, line 28, through page 20.

Additionally, the Examiner questioned about why certain dependent claims, such as claim 134 and 143, failed to make specific reference to the inclusion of a fatty acid. Applicant’s representative responded that the main claim specified a fatty acid and thus dependent claims

were not required to, referencing 35 U.S.C. 112, 4th paragraph. Additionally, it is noted that vegetable oils such as soy bean oil inherently have some amounts of fatty acids. See attached article re contents of soy bean oil.

Accordingly, it is submitted that claims 96, 98, 106-108, 110, 112, 118-122, 131-132, 134-135, 138-154 are in condition for allowance.

B. Reintroduction of Elias J. Anaissie as Inventor

Upon the filing of the present application in October, 1999, the Applicant submitted a "Statement Requesting Deletion" of Dr. Anaissie as an inventor, based on the determination that Dr. Anaissie's contribution involved the pimaricin aspect of the present invention, which was not then being claimed. However, as the present case now includes a claim to pimaricin it is now appropriate to re-introduce Dr. Annaissie as an inventor. Applicant notes that the original declaration submitted in the present case included execution by both Dr. Andersson and Dr. Annaissie, so it is believed that no additional formal paperwork is required. To effect the re-introduction of Dr. Anaissie as an inventor, Applicant encloses an appropriate statement re same.

C. Claim Rejections/Obviousness

In that claim 121 was not included in the obviousness rejection, it is believed that this rejection is now moot.

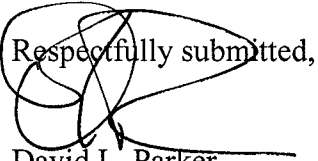
D. Provisional Obviousness-Type Double Patenting

In that USSN 10/439,252 is not currently issued, it is believed that the present rejection is not yet ripe.

E. Conclusion

Applicants respectfully request favorable consideration of this case in view of the above. Should the Examiner have any questions, comments, or suggestions relating to this case, the

Examiner is invited to contact the undersigned Applicant's representative at (512)-536-3055.

Respectfully submitted,


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SOYBEAN OIL

- Oil Extraction Methods
- Oil Purification Methods
- Commodities Used, Methods for Each and Yield of Oil
- Uses of Soybean Oil
- Oil Packaging and Shelf life
- Developing Technologies

Created by: Melinda Semon, Molly Patterson, Peter Wyborne, Airica Blumfield, Antonia Tageant

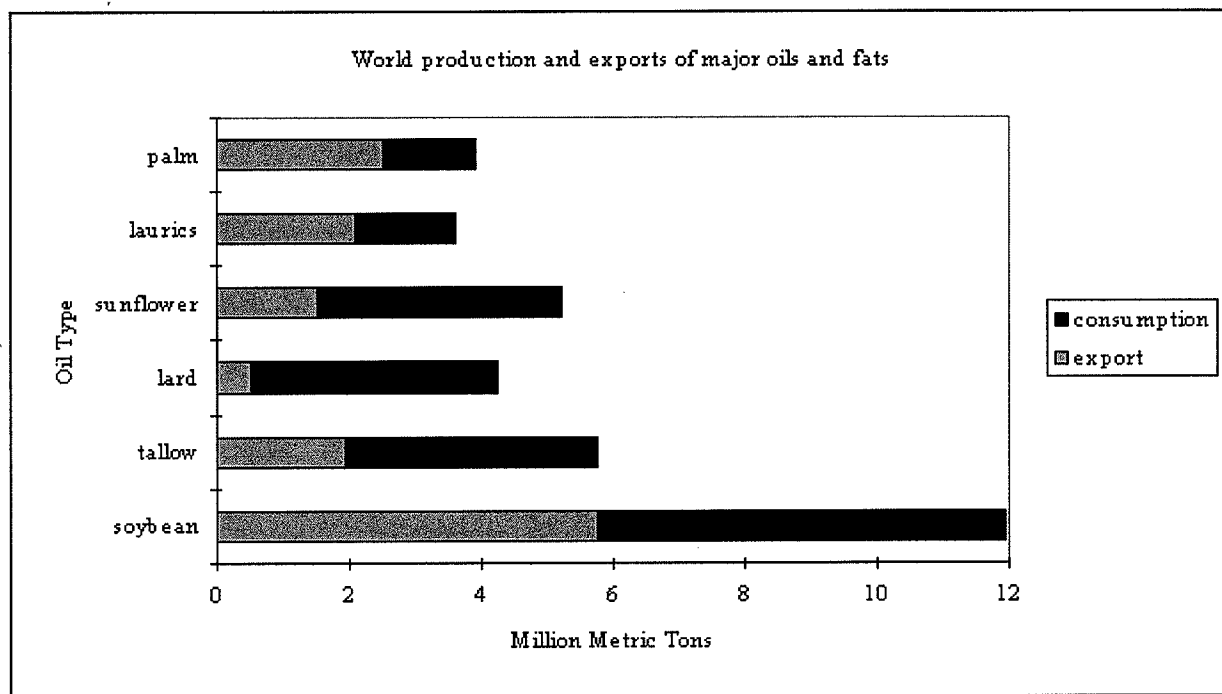
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Introduction

Soybeans (*Glycine max*) are native to Northeastern Asia and were first introduced into the United States in 1765 (Soybean Research Advisory Institute, 1984). Today, the world's largest producer of soybeans is the United States with the majority of cultivation located in the midwestern and southern United States (Comptonis, 1995). Soybeans are the second most valuable crop in the United States behind corn (Soybean Research Advisory Institute, 1984) and since 1970 the United States has produced, on the average, more than 1.5 billion bushels of soybeans per year (Comptonis, 1995). Two main products are processed from soybean: oil and the dry solid residue known as meal. According to The Soybean Research Advisory Institute, (1984) one-fourth of the world's supply of oil comes from soybeans. The oil is used to make many edible products such as salad and cooking oils, shortenings and margarines (Erickson *et al.*, 1980). Below is a graph of various oils processed in the United States and the percentage used for exports and for consumption (Erickson *et al.*, 1980). The oil content of soybeans is around 20% dry basis. Soybeans are the world's largest oilseed crop, with about 13 million tons of oil produced per year (Patterson, 1989). Soybeans are in high demand due to their high protein and oil content (Erickson *et al.*, 1980).

Figure 1. Oils processed in the United States.



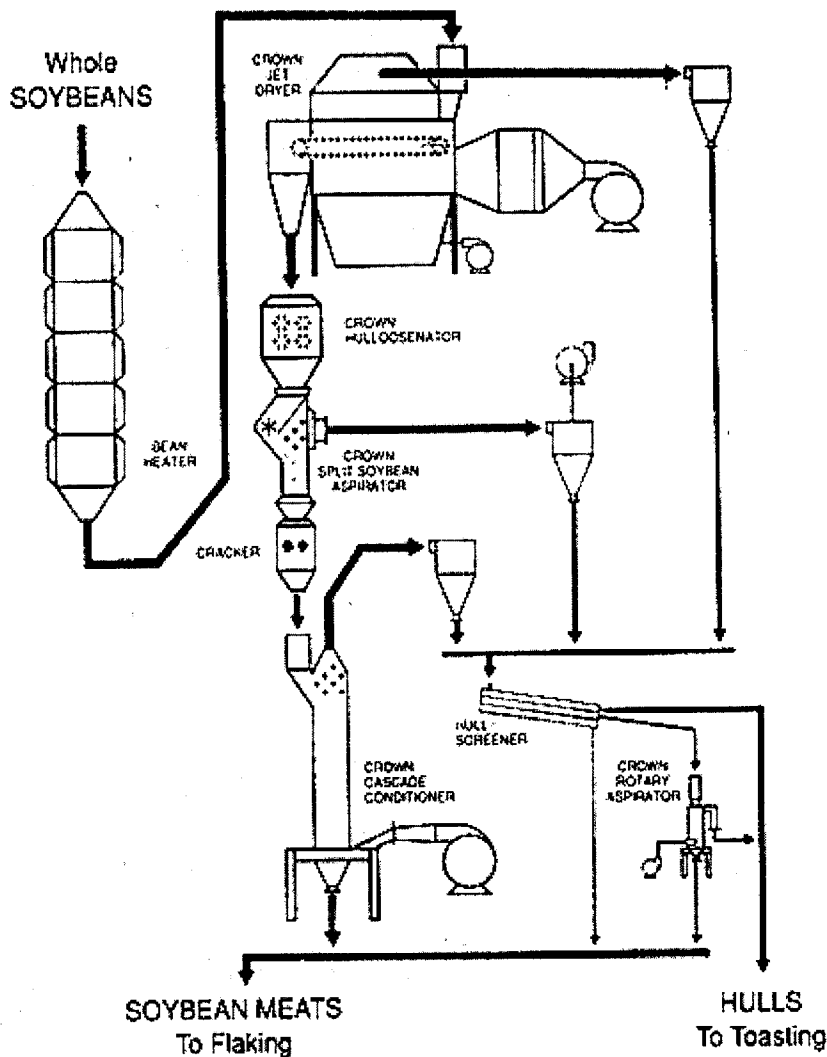
(Erickson *et al.*, 1980)

Extraction

Pre-treatment

Soybeans must be carefully cleaned, dried and dehulled prior to oil extraction (United Nations, 1977). Figure 2 depicts a soybean dehulling system (Carlson and Scott, 1991). The presence of hulls during oil extraction will result in a lower oil yield due to the absorption of the oil into the particles (Allen *et al.*, 1982). Initially, the soybeans are fed into cracking rolls to crack the beans, followed by separation of the hulls with the use of shaker screens and aspiration (Erickson *et al.*, 1980). The lighter hulls are removed from the heavier beans and kernels, with the use of fan aspiration and screens to strain for heavy objects (Allen *et al.*, 1982). Magnets are used to separate any metals. The extraction of the oil is facilitated by conditioning the beans through the application of indirect steam to adjust the moisture content and temperature (United Nations, 1977). The cracked beans are exposed to temperatures to approximately 74 - 79 C for 30 - 60 minutes (Erickson *et al.*, 1980) prior to using smooth-surface rollers to flatten into large flakes of uniform thickness (Allen *et al.*, 1982). The purpose of the conditioning is the heat denaturation and subsequent coagulation of proteins present in addition to the coalescence of oil droplets and reduction in the affinity of oil for the solid materials, making it easier to extract (Allen *et al.*, 1982).

Figure 2. Diagram of a dehulling system for soybeans



Provided by Crown Iron Works Co. (Carlson and Scott, 1991).

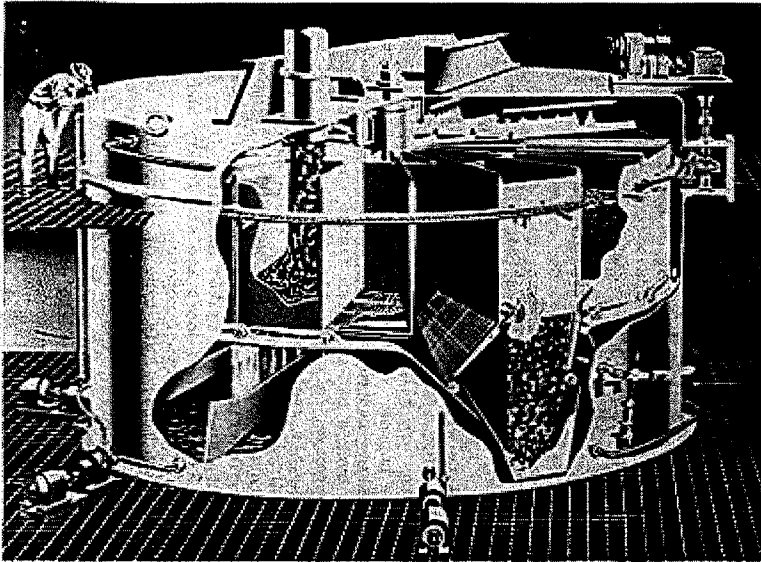
Extraction

There are three main methods for extracting oil from soybeans. These procedures are hydraulic pressing, expeller pressing and solvent extraction (Erickson *et al.*, 1980). Hydraulic pressing is one of the oldest pressing methods. This is a batch press procedure that requires hand labor and currently is no longer used for soybeans. Expeller pressing has replaced the hydraulic pressing procedure for extraction of oils. Soybeans are not commonly used in this method either.

Solvent extraction of oil seeds can be performed by equipment of either percolation-type or immersion-type. Percolation extractors are considered to be more efficient than immersion extractors because they are able to handle large capacities of product in limited areas of space. One commonly used percolation extractor is the rotary extractor (Figure 3), and enclosed vertical system that moves perforated baskets using a rotary motion around a central vertical shaft (Erickson *et al.*, 1980). Figure 4 illustrates a percolation extraction cell (Mounts and Pryde, 1983). The liquid solvent (hexane) is pumped over a bed of flakes, percolates down through the bed and leaves through the bottom through a perforated plate,

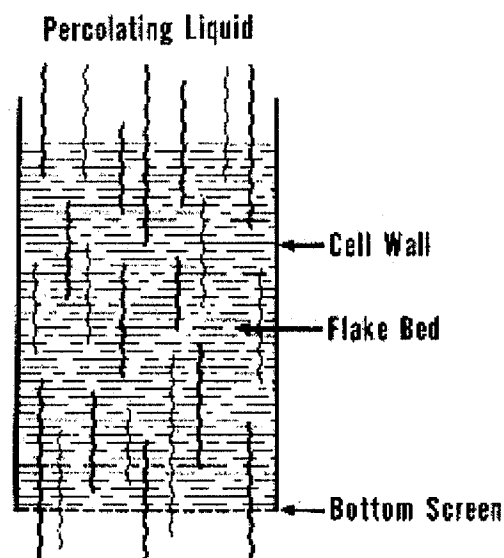
mesh screen, or wedge wire screen bar system. "Flake thickness is a factor in oil removal efficiency. An increase from 0.02 to 0.06 mm decreases the extraction rate 80 times" (Caldwell, 1980). At the end of the extraction cycle the flakes are allowed to drain and are dropped into the discharge hopper. Miscella is pumped counter-current to the flow of the flakes. Counterflow is very important to solvent extraction (as well as desolventizing) as it helps to remove oil more efficiently than parallel-flow systems. The miscella becomes richer as the oil is extracted from the soybean flakes.

Figure 3. Drawing of a solvent extractor



Taken from The Handbook of Soy Oil Processing and Utilization, 1991 (Provided by Dravo Chemical Plants Division, Pittsburgh, PA).

Figure 4. Percolating Liquid



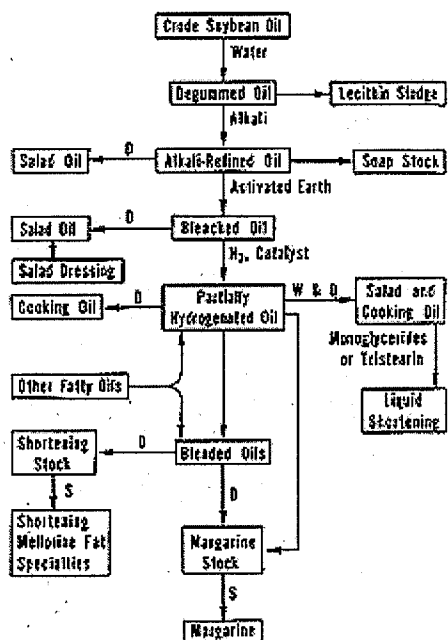
*Adapted from Mounts and Pryde, 1983.

The extracted flakes contain about 35% hexane, 7% to 8% water and 0.5% to 1.0% oil. For processing into livestock meal or edible soy products, solvent is reclaimed from the flakes in a desolventizer-toaster (D-T) unit. The miscella leaving the extractor contains about 25% to 30% oil. After it is filtered to remove suspended fines, the solvent is reclaimed through a series of evaporators. The first stage evaporator yields miscella containing 65% to 78% oil. The second stage evaporator yields miscella containing 90% to 95% oil. Vapors from both evaporators are recovered through condensers and recycled back to the extractor. Removal of final solvent is accomplished through an oil stripper. The oil stripper consists of a steel cylindrical vacuum column in which live steam flows upward counter-current to the flow of oil. The oil, free from extraction solvent, is cooled to ambient temperature and pumped to storage for further processing (Mounts and Pryde, 1983 and Scott, 1991).

Purification

After extraction and concentration, the crude soybean oil contains many oil-insoluble and oil-soluble impurities that must be removed (Erickson *et al.*, 1980). Oil-insoluble material may be removed through filtration; however, the soluble materials must be removed by implementing several different techniques listed below. Figure 5 depicts a flow diagram for the manufacture of edible soybean oil products (Erickson *et al.*, 1980).

Figure 5. Flow diagram for the manufacture of edible soybean oil products



Key: D= deodorization, W= winterization, S= solidification, H₂= hydrogenation.

(Taken from Erickson *et al.*, 1980)

Degumming and Lecithin Recovery

Degumming is a process that involves mixing crude soybean oil with 2-3% water, gently agitating for 30 - 60 minutes (being careful to prevent the introduction of air and subsequent oxidation of oil) at a temperature of 70 °C (Erickson *et al.*, 1980). This hydrates phosphatides and other impurities that can be settled, filtered, or centrifuged out from the degummed oil. This process is commonly done to recover phosphatides to make soybean lecithin and also to remove materials that can settle out during shipment or storage of pure oil. The gum sludge material is processed into lecithin, after drying and bleaching, or added back to wet soybean meal. Lecithin is often desirable in a food due to its wetting, emulsifying, colloidal, antioxidant and physiological properties (Erickson *et al.*, 1980).

Alkali Refining

Continuous automated refining operations are used to remove objectionable impurities that may affect oil quality. Caustic soda is used in refining to remove free fatty acids, phosphatides and gums, colorants, insoluble matter and other material. The crude oil is pumped through a heat exchanger to adjust the temperature to 38 °C and a small sample is taken after mixing thoroughly. The free fatty acids (FFA) content must be determined since the weight percent of caustic added depends on the FFA present. Commonly, 0.10 - 0.13% caustic is added on a dry basis and then thoroughly mixed to ensure saponification of the FFAs, hydration of the phospholipids and reactions with color pigments. This mixture is heated to 75 - 82 °C and centrifuged to separate out the caustic from the refined oil. Next, the refined oil is heated to 88 °C and mixed with 10 - 20% soft water that has been heated to 93 °C. High shear forces are exerted on this water-oil mixture and the mixture then passes through two centrifuges to separate into heavy and light phases (Erickson *et al.*, 1980).

Bleaching

Normally, a continuous vacuum bleaching process is employed by adding activated earth to the refined oil to remove color, odor, other impurities and residual soap (Erickson *et al.*, 1980). Approximately 1% of an adsorbent such as Fuller's earth or activated carbons is added to the oil. The slurry is then pumped into a vacuum system under 15 inches Hg for 7 - 10 minutes and subsequently heated to 104 - 166 °C by passing through an external heat exchanger into an empty tank under agitation for 10 minutes. The slurry is then filtered, cooled and pumped to a holding tank (Erickson *et al.*, 1980). Shortenings are typically bleached to a white color while margarines, and salad and cooking oils can remain yellow-tinged. The odor, flavor, and oxidative stability of the bleached soybean oil are greatly improved (Erickson *et al.*, 1980).

Hydrogenation

Hydrogenation of soybean oil increases the melting point, improves stability of the oil from the effects of oxidation and flavor deterioration (Erickson *et al.*, 1980) by reducing linolenic acid to linoleic acid and linoleic acid to oleic acid (Haumann, 1984). The hydrogenation will give different degrees of hardness for specific products desired (Haumann, 1984). This reaction occurs between high purity hydrogen gas, a catalyst (such as nickel) and the fats and oils resulting in the addition of hydrogen to

unsaturated bonds causing saturation. Hydrogenation occurs in a vacuum-pressure vessel containing oil into which the hydrogen gas is dispersed as fine bubbles while heating the mixture and agitating. When the desired hydrogenation is obtained, the mixture is cooled, the catalyst is filtered out to obtain a solution that is completely clear (Erickson *et al.*, 1980). The partially hydrogenated oils remain liquid and the more highly hydrogenated soybean oil is hardened (Erickson *et al.*, 1980).

Deodorization

Deodorization is a high temperature, high vacuum, steam-distillation process that is necessary for the removal of volatile flavor and odor compounds to transform the oil into a bland-tasting clear liquid desirable to consumers (Erickson *et al.*, 1980). The removal of the free fatty acids will also increase stability of the oil. The oil is sparged with steam at high temperature and vacuum that also prevents the introduction of oxygen and thus oxidation from occurring during the deodorization process (Carlson and Scott, 1991).

Winterization

Soybean oil use for application as cooking oil must be winterized to meet requirements of the American Oil Chemists' Society cold test. Winterization is a process performed on partially hydrogenated soybean oil that involves the chilling of the oil to allow the solid portion to crystallize and the subsequent filtration of the two phases (Erickson *et al.*, 1980). Winterization is a form of fractionation or the removal of solids at selected temperatures. It involves the removal of a small quantity of crystallized material from edible oils by filtration to avoid clouding of the liquid fractions at refrigeration temperatures. Oil is chilled slowly to about 6 C during a 24-hr period. Cooling is stopped and the oil/crystal mixture is allowed to stand for 6 to 8 hrs. The oil is filtered, yielding 75 - 80% liquid oil and the byproduct stearine which is used for shortening manufacture (Mounts and Pryde, 1983).

Dewaxing

Methods such as dewaxing and solvent fractionation are also used to clarify oils. Dewaxing squeezes or presses liquid oil from solid fat by hydraulic pressure to produce hard butters and specialty fats. Solvent fractionation involves the crystallization of desired fractions from a mixture of triglycerides dissolved in a suitable solvent. Fractions may be selectively crystallized at different temperatures, separated and the solvent removed for a final product of specific triglyceride or fatty acid composition (Mounts and Pryde, 1983 and Ziller *et al.*, 1994).

Commodities Used, Methods for Each and Yield of Oil

The value of the oil seed lies in its content of high quality oil. Soybeans are high in both oil and protein. Its composition can be approximated as follows (Erickson *et al.*, 1980):

Table 1. Composition of Soybeans

Protein	40%
Lipid	20%
Cellulose and Hemicellulose	17%
Sugars	7%
Crude Fiber	5%
Ash (dry weight basis)	6%

(Erickson *et al.*, 1980):

Almost all soybeans harvested throughout the world are processed to oil and meal products through the solvent extraction process explained above. Some equivalent units for soybean products are listed in Table 2.

Table 2 - Some Equivalent Measurements for Soybeans

Unit Equivalent

1 bushel of beans 60 lb of beans

1 bushel of beans 10.7 lb of crude oil

1 bushel of beans 47.5 lb of meal

1 bushel of beans 39 lb of flour

1 bushel of beans 20 lb of concentrate

1 bushel of beans 11.8 lb of isolates

1 short ton of beans 33.33 bushels beans

1 short ton of soybean meal 42.08 bushels of soybeans

1 long ton of beans 37.33 bushels of beans

1 long ton of soybean meal 47.13 bushels of soybeans

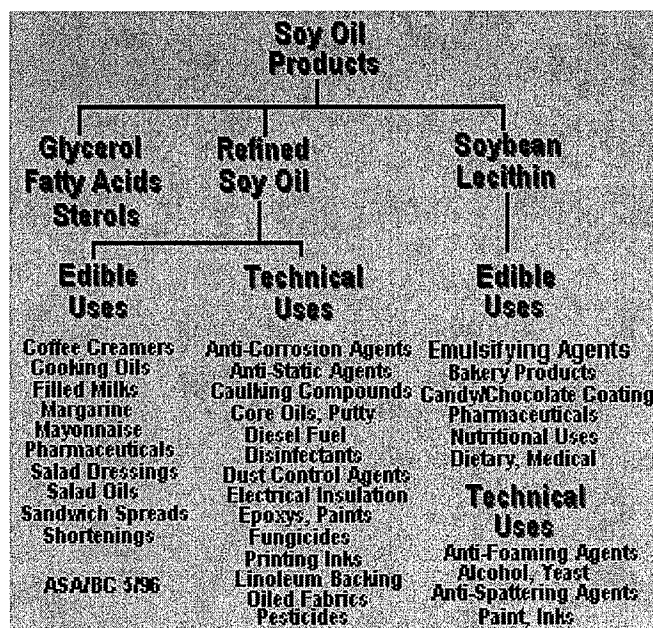
1 metric ton of soybean meal 46.39 bushels of soybeans

*Adapted from Mounts and Pryde, 1983.

Uses of Soybean Oil

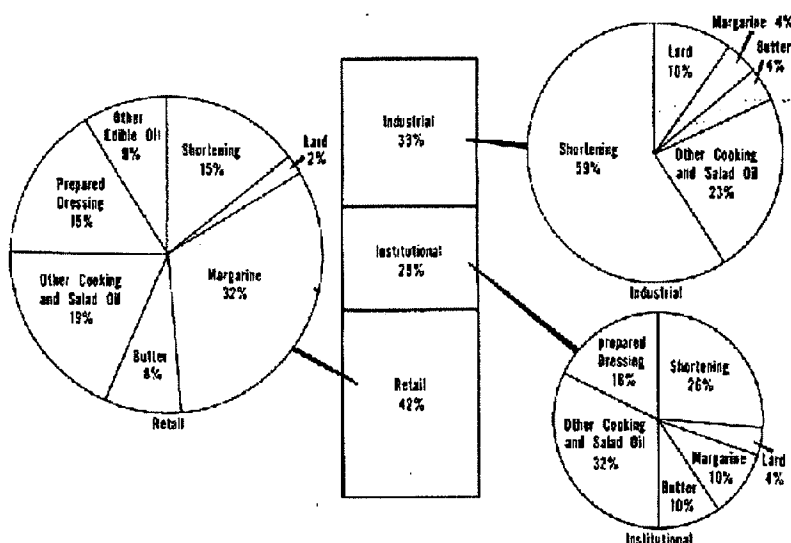
Soybean oil is the dominant vegetable oil used domestically in edible oil products (Erickson *et al.*, 1980). Applications of soybean oil fall into two main categories: edible fat products meant for human consumption and industrial fat products used for technical purposes.

Figure 6. Uses of soybean oil



(ASA Webmaster, 1996. http://www.oilseeds.org/asa/uses_soy.htm).

Figure 7. Edible Oil Products Used by Trade Sector



(Adapted from Mounts and Pryde, 1983.)

Advantages and Disadvantages to Soybean Oil

There are several advantages of extracting oil from soybeans, as compared to other oils. The oil extracted is high in unsaturation and is very temperature stable remaining in a liquid oil form (Erickson *et al.*, 1980). Soybean oil also can be processed to remove undesirable components such as

phosphatides, trace metals and soaps (Erickson *et al.*, 1980). By removing these undesirable components the stability of soybean oil is increased. Also in soybean oil there are antioxidants naturally present which are not extracted. Leaving these antioxidants present helps to prevent the oxidative rancidity which may occur in the lipids present in the oil. Antioxidants also help to reduce free radical damage in the body (Jacob, 1994). Though there are advantages, there are also several disadvantages to processing soybean oils compared to other oils. Due to the very high content of phosphatides, about 2%, these must be removed during processing (Erickson *et al.*, 1980). Also soybean oil contains 7 - 8% linolenic acid which can be reduced by hydrogenation steps in the process. This high content of linolenic acid can cause development of off flavors and off odors.

Oil Packaging and Shelf Life

Packaging

Soybean oil as a vegetable shortening is packaged in 1 pound and 3 pound retail packages or 50 pound polyethylene lined cubes. Liquid forms of soybean oil are packaged in 35 pound or 1 gallon plastic jugs. At the processing plant, soybean oil can be stored in large iron or stainless steel tanks (Lawson, 1995). Soybean oil has a shelf life of over a year (Patterson, 1989).

Bottled edible oils will undergo flavor and oxidative deterioration when exposed to light (Erickson *et al.*, 1980) and therefore should be packaged in brown glass bottles to increase shelf life. The use of dark or opaque packaging is important for shelf life of the oil. Packaging in clear glass or translucent plastic markedly deteriorates the quality of the oil after a few short hours under fluorescent light (Erickson *et al.*, 1980). The containers are filled completely and nitrogen flushed into the bottles to reduce the chances of oxidation. Margarines are commonly packaged in opaque plastic tubs and stored under refrigeration. Packaging in metal containers should be avoided due to possible reactions of the metal with the oil.

Shelf Life

Soybean oil is oxidatively unstable in its unhydrogenated form (Soybean Research Advisory Institute, 1984). Factors thought to contribute to oil instability include triglyceride composition and fatty acid content (especially linolenic acid), enzymatic activity occurring in the bean itself and other factors (Soybean Research Advisory Institute, 1984). Oil stability can be increased through purification and proper handling of oil.

Flavor Reversion

Flavor reversion is a chemical process, characteristic to linolenate-containing oils such as soybean, involving autooxidation of linolenate leading to unfavorable organoleptic qualities described by many as green beany- or grass- flavored and later, as the flavor reversion progresses, is described as fishy-flavored. This poses a great problem to shelf-stability of soybean oils since 7 - 8% of soybean oil contains linolenic acid. Flavor reversion also occurs from light exposure. To improve stability, partial and selective hydrogenation is carried out to lower the linolenic acid concentration. Improvements have been made in the flavor and oxidative stability of the unhydrogenated and partially hydrogenated oils (Erickson *et al.*, 1980).

Developing Technology

Attempts to reduce waste material production, in addition to the management of waste material, is also

being developed. One of the biggest changes in oil plant production has been the switch from caustic refining to physical refining. In physical refining the caustic soda treatment, used for the removal of free fatty acids, is eliminated and a vacuum steam distillation process removes free fatty acids as well as deodorizes by removal of volatiles. The physical refining of soybeans is difficult due to the high and variable phosphatide content of soybeans, especially nonhydratable phosphatides or NHP. This in turn has led to the development of improved degumming treatments. Unless lecithin is a required byproduct of soybean oil production, it is now common to use various acid degumming methods to improve NHP removal and facilitate physical refining (Caragay, 1983 and Carson, 1991).

Another alternative to acid and alkali refining, developed by WIR, Grace & Co., is silica refining. Silica has a higher ability to adsorb soap and phospholipids than traditional clays. Its adsorption qualities can even be enhanced by prior adsorption of soaps. The silica refinement process is based on this feature: a reduced amount of caustic, sufficient to create 500 ppm soap, is added to water degummed oil. Silica is then added after the oil is filtered in a packed bed of bleaching clay and filter aid. Silica refinement does not produce any effluent waters and provides an overall cost advantage (refine and bleach in one step) (Carson, 1991).

Other new processing aids include the use of enzymes for extraction purposes and the use of expanders to produce collets, as opposed to seed flakes, also for extraction purposes. Enzymes produced from the microorganisms of *Bacillus* and two strains of *Aspergillus niger* have been shown to aid in physically releasing oil globules from the protein and polysaccharide matrix of oil seeds. The yield of oil increases with increasing enzyme concentration (until concentrations reach between 2 to 3%). Expander equipment can be added to system operations before extraction to improve drainage and lower the solvent carry-over to the desolventizer-toaster (DT). Expanders increase the bulk density of oilseeds to increase extraction capacity by 15 to 30%. The retention time to extract collets is less than that required to extract cake-type products. This will either lower the residual oil content of the meal or increase capacity. Research is also being conducted to compare the use of extruded collets to flakes and their effects on NHP in soybean oil (Caragay, 1983 and Scott, 1991).

Conclusion

Due to increasing demand and an increase in usage of oils, the oil industry is processing more oil than ever before and every oil type has its own characteristics. Soybean oil is the most processed, consumed and exported oil in the United States (Erickson *et al.*, 1980). Soybean oil provides food for humans and animals and material for many industrial uses. For decades, the industry has used the same basic principles to extract oil from oilseed and process crude edible oil. The industry's goal, now, is to utilize advances in technology to extract, refine and develop oil products into something better, faster, and cheaper (Carson, 1991).

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